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REMARKS

In response to the Final Office Action mailed July 19, 2006, and Advisory Action mailed October 5, 2006, please enter the amendments above and consider the following remarks along with the RCE submitted herewith. Applicant requests that that amendment filed on September 19, 2006 in response to the Final Office Action not be entered in the present application. In the Final Office Action, claims 1-21, 23-31, 33-38, and 78-99 were pending, and claims 15-21, 23-31, 34, 36, 37 and 89 were withdrawn as being directed to a non-elected invention. Claims 1-14, 33, 35, 38, 78-88, and 90-99 stand rejected. In this response, claims 1 and 78 have been amended and are in condition for allowance along with the remaining claims. Reconsideration of the present application as amended and in view of the remarks that follow is respectfully requested.

Claims 1-14, 33, 35, 38, 78-88 and 90 were rejected under 35 USC §112, first paragraph as failing to comply with the written description requirement. It was asserted that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, possessed the claimed invention. Specifically, it was asserted that applicant fails to disclose a body having a length extending "extradiscally" to a second vertebral body. It was further asserted that "extradiscally" is considered new matter since it was never presented in the original claims and specification.

The assertion is traversed. The examiner is directed to Fig. 1. One of ordinary skill in the art would clearly understand what is disclosed therein is a portion of implant 30 that is located outside disc space D with a length to extend between the vertebrae. Furthermore, one of ordinary skill in the art would understand from the specification that the implant extends outside the disc space between the vertebrae. On page 8, lines 11-13 it is disclosed the "implants have a low profile and are conformable to the spinal anatomy to minimize intrusion into the surrounding tissue and vasculature." On page 8, lines 17-19 it states the stabilization device 28 includes "a flexible implant 30 that extends along the anterior aspects of vertebrae V1 and V2...." The prefix "extra" means outside or beyond. See extra. (n.d.). *The American Heritage® Dictionary of the English Language, Fourth Edition*. Retrieved September 18,

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2006, from Dictionary.com website: <http://dictionary.reference.com/search?q=extra>. The specification and drawings clearly disclose an implant extending outside the disc space between vertebrae. Therefore, the rejection is traversed.

Despite the traversal of the rejection under 112, first paragraph, in order to moot the rejection and place the claims in condition for allowance to expedite prosecution of the present application, the word "extradiscally" has been deleted from claims 1 and 78.

Claims 1-14, 33, 35, 38, 78-88 and 90-99 were rejected as being anticipated by U.S. Patent No. 6,607,530 to Carl et al. Amended claim 1 recites "an implant having a first end and an opposite second end, at least a portion of one of said first and second ends structured for positioning in use in a tunnel formed in a first vertebral body; and at least one anchor sized to be embedded within the first vertebral body without protruding from the first vertebral body for attaching said at least a portion of said one of said first and second ends of said implant to the first vertebral body when positioned in the tunnel with said implant including a body having a length and structure to extend from the tunnel in conformance with the first vertebral body to a second vertebral body."

Carl discloses an implant 160 that extends into vertebral bodies through tunnels formed in the vertebral endplates of the vertebral bodies. The implant is provided with a size and shape that corresponds to the size and shape of the pre-formed tunnels, and exits the tunnels at the endplates of the vertebrae so that the implant is located in the disc space and not along either of the vertebrae. The Examiner refers to Figs. 6a-b and asserts that the curvature of the implant discloses means for conforming. The assertion is traversed. Implant 160 has a size and shape that corresponds to the size and shape of the tunnel. However, implant 160 does not include any structure to extend from the endplate in conformance with any vertebra. Rather, the implant 160 extends from the tunnel into the disc space and does not include any length or structure to extend from the tunnel in conformance with any vertebral body.

The Final Office Action asserts that column 13, lines 14-17 and Fig. 10 of Carl et al. disclose "the implant can be arranged so as to include a biting or expansion element(s) that can be driven out in a lateral direction so as to engage the bony structure of the vertebrae" and that this somehow discloses the implant conforms to the vertebral body outside the tunnel. The rejection is traversed. It is not understood how the lateral biting or expansion element

that is driven laterally into a vertebra in the tunnel could be properly considered to conform to the vertebral body outside the tunnel. An element that bites or is expanded to engage the vertebrae does not conform to the vertebrae, but rather deforms the vertebrae in order to bite or engage the vertebrae. Furthermore, such biting or expansion of implant 160 would necessarily occur in the tunnel in which implant 160 is positioned, and therefore would not conform implant 160 to the vertebral body outside the tunnel. Accordingly, Carl cannot anticipate claim 1 and withdrawal of this basis of the rejection is respectfully requested.

The Final Office Action asserts, concerning claims 2-14, 33, 35 and 38, that the screw (400) of Carl et al. threadingly engages the ends of the implant as set forth in column 13, lines 10-13, and that this somehow discloses "wherein at least one anchor extends along and threadingly engages said one of said first and second ends" of the implant. The assertion is traversed. The Final Office still fails to provide any indication of how screw 400 is considered to disclose an arrangement that extends along the implant. Screw 400 extends laterally through the implant in a substantially transverse relation to the implant. Claim 2 recites "wherein said at least one anchor extends along and threadingly engages said one of said first and second ends of said implant." Since fasteners 400 do not extend along the implant, Carl cannot disclose this feature recited in claim 2. Allowance of claim 2 and other claims depending from claim 1 is requested.

With respect to claim 78, the Final Office Action points to Figure 10 and asserts it discloses "the end portions of the implant being relatively angled relative to one another." However, this is not what is being claimed. What is claimed is "said one of said first and second ends and said portion of said implant are flexible and angled relative to one another". The portion in claim 78 is not an end portion, but is "a portion between said first and second ends sized to extend from the first vertebral body to a second vertebral body." This arrangement of elements is not disclosed in Carl. In contrast, Fig. 10 shows the portion of implant 700 that extends between the vertebrae is V-shaped. The end portions in Carl that extend into the vertebrae from the V-shaped portion are formed as linear, non-angled extensions of the V-shaped portion. Furthermore, the V-shaped implant is rigid. See col. 15, lines 2-4 and lines 13-15. Accordingly, Carl cannot anticipate claim 78 and withdrawal of this basis of the rejection of the same is respectfully requested.

Furthermore, claim 78 recites "said one of said first and second ends and said portion of said implant are flexible and angled relative to one another and said portion includes a length sized to extend from the first vertebral body toward the second vertebral body with the one of the first and second ends and said portion being structured to conform to the vertebral body when oriented for positioning into the first vertebral body in the tunnel." As discussed above with respect to claim 1, Carl et al. discloses implant 160 that extends from the tunnel into the disc space and does not include any length or structure to extend from the tunnel in conformance with any vertebral body. Accordingly, claim 78 is allowable for this additional reason as well.

Claims 79-88, 90 and 99 depend from claim 78 and were rejected in the Final Office Action. These claims distinguish Carl at least for the reasons claim 78 does. Additional reasons can be provided to support the independent patentability of these claims. For example, claim 81 recites "wherein the first and second ends extend in opposite directions from one another and are angled relative to said portion such that when engaged to the respective vertebral bodies the first and second ends each form an angle ranging from about 0 degrees to about 80 degrees relative to an axial plane taken at an entry location of the respective first and second ends into the respective vertebral body." There is no disclosure in Carl of two ends that are angled relative to a portion sized to extend between vertebrae. Also, Carl discloses that the anchors 400 extend transversely to the ends of the implant, and cannot anticipate claim 87, which recites "wherein said at least one anchor extends along said one end of said implant." Claim 99 recites "wherein said at least one anchor extends along and threadingly engages said one of said first and second ends of said implant." As discussed above with respect to claim 2, Carl does not disclose any such engagement relationship between fasteners 400 and implant 160. Accordingly, allowance of the claims depending from claim 78 is also requested.

The Final Office Action also asserts with respect "to the manner in which the anchor extends in relation to the implant, Applicant is reminded that the manner in which a device is intended to be employed does not differentiate the claims apparatus from the proper art apparatus satisfying the claimed structural limitations." Applicant is not claiming the manner in which the device is to be employed. Rather, what is being claimed is a structural

arrangement between the anchor and the end of the implant. This arrangement of elements is not disclosed in Carl. The law of anticipation requires "[A]n invention is anticipated if the same device, including all the claim limitations, is shown in a single prior art reference. Every element of the claimed invention must be literally present, arranged as in the claim." Richardson v. Suzuki Motor Co. Ltd., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Accordingly, the assertion is traversed and withdrawal of the rejections based thereon is respectfully requested.

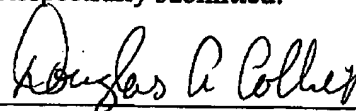
Claim 91 also distinguishes Carl since it fails to disclose, among other features, "at least a portion of one of said first and second ends including means for conforming to a first vertebral body in a tunnel formed in a first vertebral body". Carl also fails to disclose "said means for conforming further having a length extending from the tunnel to conform to the first vertebral body outside the tunnel." As discussed above with respect to claim 1, Carl discloses an implant that is positioned in tunnels that are formed to match the shape of the implant. The portion of implant 160 exiting the tunnels are situated between the endplates, and have a predetermined size and shape that is V-shaped or arced shape and do not conform to a vertebra outside the tunnel. There is no disclosure that implant 160 is structured to conform or provides any means for conforming as recited in claim 91. Accordingly, there is no disclosure in Carl of an implant as recited in claim 91 and withdrawal of this basis of the rejection is respectfully requested.

Claims 92-98 depend from claim 91 and allowable at least for the reasons claim 91 is allowable. Additional reasons can be provided to support the independent patentability of these claims. For example, Carl discloses the implant extends through the disc space between vertebrae, and does not disclose claim 97 which recites "wherein said body is structured for positioning on anterior faces of the first vertebral body and the second vertebral body when said first and second ends are positioned in respective ones of said tunnels." The Final Office Action refers to Fig. 10. However, in Fig 10 the apex of the V-shaped implant is situated in the disc space, and the implant in Fig. 10 is disclosed as a rigid implant which is not structured for positioning on anterior faces of the first and second vertebrae when the ends are in the tunnels. See col. 15, lines 2-4 and lines 13-15. Claim 98 depends from claim 91 and recites "wherein said at least one anchor extends along and threadingly engages said one of

said first and second ends of said implant." As discussed above with respect to claim 2, Carl does not disclose any such engagement relationship between fasteners 400 and implant 160 where the fasteners 400 extend along the implant. Accordingly, allowance of the claims depending from claim 91 is also requested.

In view of the above amendments and remarks, it is believed that claims 1-21, 23-31, 33-38 and 78-99 are in condition for allowance, and a Notice of Allowance is hereby solicited. The Examiner is welcome to contact the undersigned to resolve any outstanding issues with regard to the present application.

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